QI Meeting Minutes

October 23, 2008 9:30 – 11 am Room 123

Attendees: Peter Belanger, Lauren Catalogna, Marcia Stowell, Jennifer Jenner, Karen Chen, Paul Elvin, Joseph Peppe, Tracy Stiles, Peter Piro, Annie Dookhan, Felipe Alfonso, Alan Rubin, Pat Jacobsen, Jill Clemmer, Betsy Szymczak, Arthur Kazianis, Alan Borne, Cheryl Gauthier, Julianne Nassif, Dina Caloggero, Xingtai Wang, Peggy DiNatale

Minutes prepared by Peggy DiNatale, 11/17/08

Action items:

1. Lab Supervisors should complete the CDC send out form (attached to the minutes) and return it to Peggy DiNatale by November 25. The form can be submitted either electronically or in hard copy.
2. The flowchart for the hiring process is attached.
3. Lab Division Directors must submit a line listing of the QI projects from 2007 and 2008 for each Division. The line listing should include the specific lab and the title of the QI project.

Meeting Minutes

A. Follow up on Items from previous meetings:

1. **Follow up to CDC send out turn around time project – ask labs to collect information again to see if there has been any improvement in the turn around times:**

   The CDC thanked us for alerting them to the problem. They had started a QI committee and this issue will be addressed by the CDC QI group. We are collecting data again, before receiving any feedback, because sometimes an improvement will be noticed after a problem is identified. We will collect data overtime to monitor any improvements and to monitor the sustainability of the improvements.

   The data collection sheet will be sent out to all Laboratory Supervisors to complete. The form is available in hard copy and in an electronic version. The electronic version is a fill- able form. If you have trouble completing the form, please contact Peggy DiNatale at ext. 6243.

   The send outs to be counted include any specimens sent out that are still pending. If you identify specimens that are pending more than 9 months, please complete page 2 of the form. This will allow us to identify specimens that we want CDC to pay special attention to from this data collection.

   Peggy will send these forms out and the email will include a completion date.

B. New Items:

1. Hiring process discussion as follow up from the Laboratory Quality Series

A draft version of a flowchart describing the various steps in the hiring process was distributed. This flowchart was developed by Peggy DiNatale, Dina Caloggero, Carol Cormier and Lauren Catalogna, as a result of feedback from the staff during the Quality Series Overview session.

Minor revisions were discussed and these will be incorporated into the flowchart. This will be distributed with the meeting minutes.

2. CLIA:

A. Discuss any comments / concerns as a result of the presentation by Charlie Reynolds on Pre-analytical and Post-analytical CLIA regulations

Discussion: Session was informative.

B. QI study project by labs - Each Lab will be asked to briefly describe the QI projects for 2008.

Each lab described the QI projects that are in process in their labs.

Each Supervisor should send a listing of the title of their QI projects to Peggy DiNatale. Each lab should have a list for 2007 and 2008.

3. Provide an update of findings from the recently completed lab audits –

A. Trends or patterns observed in multiple labs audited to date:

1. SOPs: There are multiple version of the same SOP present in the SOP books presented by the laboratory during the audit. The SOP that is in use has not been approved and doesn't have a signed approval sheet. There is no SOP present. The SOP doesn't match the manufacturer instructions.
2. Verification data for new assays and/or new lots of materials (reagents, media, primer/probes, etc.):
   a. Review: The data is not signed off by the Lab Division Director before being put into use.
   b. Organization of data: The new lot verification data could not be located during the audit. The new lot verification data was stored in various different locations.

B. Checklist used by QA:

The checklist has been revised after each audit. The checklist was revised in part due to the re-organization of QA practices and it now includes the following items: personnel lists, test list and volumes, PT surveys, and QI projects. The current checklist will be used for the next few audits before any further revisions are made to the form. The QA SOP, QA.010 will be revised and updated on the P drive.

4. Discuss any concerns regarding new company that is servicing the autoclaves (Technology in Medicine - TIM): No concerns to date. Everything seems to be fine.